

Exhibit D

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE PIERCE

76 CIV. 5080

PHARMACEUTICAL SOCIETY OF THE STATE
OF NEW YORK, INC., STILL'S PHARMACY,
INC., RIIS-WALD PHARMACY, INC. and
M.F.K. DRUG CO., INC.

CIVIL ACTION

Plaintiffs NO

-against-

HUGH L. CAREY, Governor of the State
of New York, and PHILIP L. TOIA,
Commissioner, New York State Depart-
ment of Social Services.

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The plaintiffs, by their attorneys GOLDBERG & GOLDBERG
es and for their complaint against the defendants allege as
follows:

JURISDICTION AND VENUE

1. Jurisdiction is conferred on this Court pursuant
to 28 U.S.C. Section 1343, and 28 U.S.C. Section 1331. The
amount in controversy, exclusive of cost, exceeds the sum of
\$10,000.00. Declaratory and related injunctive relief are
authorized by 28 U.S.C. Sections 2201 - 2202.

2. Venue exists under 28 U.S.C. Section 1332, because
all defendants, upon information and belief, are residents of
the State of New York.

PARTIES

3. Plaintiff, the PHARMACEUTICAL SOCIETY OF THE
STATE OF NEW YORK, INC. is a non-profit corporation organized
and existing under the laws of the State of New York. It is

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a professional association representing approximately 1330 pharmacists and retail pharmacies licensed by the State of New York. By the authority granted to its officers and ~~executive~~ board, the Association brings this action on behalf of ~~its~~ members who are similarly situated to individual plaintiffs named herein.

4. Plaintiffs, STILL'S PHARMACY, INC., RIIS-WALD PHARMACY, INC. and M.F.K. DRUG CO., INC. are each a retail pharmacy licensed by the State of New York. Plaintiffs, STILL'S PHARMACY, INC. and RIIS-WALD PHARMACY, INC. are members of the PHARMACEUTICAL SOCIETY OF THE STATE OF NEW YORK, INC. Each individual plaintiff is a provider of pharmaceutical services and supplies in the Medical Assistance Program administered by the State of New York, Department of Social Services, pursuant to Title XIX of the Social Security Act, 42 U.S.C. Section 1396 et seq., commonly referred to as the "Medicaid Program".

5. Defendant, HUGH L. CAREY, is a duly elected Governor of the State of New York. In his capacity as ~~Governor~~, defendant CAREY has the authority and responsibility to ~~dictate~~ New York State's participation in the aforementioned Medicaid Program.

6. Defendant, PHILIP L. TOLA, is the duly appointed Commissioner of Social Services of the State of New York. The Department of Social Services is established as a State agency responsible for the State of New York's administration of the Medicaid Program, as provided for by Title XIX of the Social Security Act and the regulations promulgated thereunder; and defendant TOLA is directly responsible for such administration.

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NATURE OF CASE

7. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.; Title XIX of the Social Security Act, 42 U.S.C. 1396 et seq.; the Public Health Service Act, 42 U.S.C. 201 et seq.; the Constitution of the United States of America, Article I Section 8; Article 6 Clause 2; Amendment V and Amendment XIV and the New York State Administrative Procedure Act, Sections 202 and 501.

8. The Medicaid Program is established under Title XIX of the Social Security Act, 42 U.S.C. Section 1396 et seq., and provides for a program of Medical Assistance through the various states to the individuals whose economic resources are insufficient to meet the cost of necessary medical services.

9. The participation by the various States in the Medicaid Program is voluntary. New York State has elected to participate in the Medicaid Program; plaintiffs believe that the New York State Department of Social Services has been duly designated to be the single state agency responsible for the administration of the Medicaid Program, as required by 42 U.S.C. 1396 (a)(5).

FIRST COUNT

10. Title XIX of the Social Security Act, 42 U.S.C., Section 1396 et seq., requires that a state participating in the Medicaid Program must adopt an approved medical assistance plan; but, Title XIX and the regulations promulgated thereunder are silent as to the basis upon which the states are to reimburse participating providers of pharmaceutical services and supplies;

except that on August 15, 1975, the United States Department of Health, Education and Welfare promulgated 45 C.F.R. § 250.30 (b)(2), amended effective November 30, 1975, establishing that a State plan for medical assistance under Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. must prescribe an "upper limit" on payments made to pharmaceutical providers.

11. Title 45 of the Code of Regulations, § 250.30 (b)(2), requires that the upper limit for a multi-source drug shall be based upon the maximum allowable cost ("M.A.C.") of such drug, plus a dispensing fee; and the upper limit for non-multi-source drugs shall be based upon the estimated acquisition cost ("E.A.C.") of such drugs, plus a dispensing fee.

Said regulation requires that for each non-multi-source drug, the upper limit shall be established by the state, and shall be the state's closest estimate of the price generally and currently paid by providers for such drug ("E.A.C.").

Said regulation further requires that in addition to payment up to a maximum of the M.A.C. or E.A.C., the state shall also pay the providers a dispensing fee.

12. On November 15, 1974 the United States Department of Health, Education and Welfare published proposed regulations to establish standards for the payment or reimbursement for drugs in the aforesaid Public Welfare Programs, particularly Medicaid and Medicare. As one component of determining the amount of reimbursement to be paid pharmacy providers, the proposed regulations relied upon the concept of a "reasonable dispensing fee".

13. On July 25, 1975, the United States Department of Health, Education and Welfare promulgated final regulations

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incorporating this concept of "reasonable dispensing fee", to wit, 45 CFR 19.1 et seq. Subsequently, on or about April 26, 1976, 45 CFR 19.3, which was added to such regulations, became effective.

14. On or about April 26, 1976 42 C.F.R. 50.504 (b) also became effective. Said regulations set forth criteria for Department of Health, Education and Welfare to review the "reasonableness" of said dispensing fee and requires the Secretary of the Department of Health, Education and Welfare to take into account pharmacy cost components and surveys on the cost of pharmacy operations.

15. In establishing set dispensing fees the regulations promulgated by the Department of Health, Education and Welfare specifically mandate that the State must take into consideration the results of such surveys of the costs of pharmacy operations; and that such surveys should be conducted periodically by the State taking into consideration such pharmacy operational data as overhead, professional services and profits.

45 C.F.R. 250.30 (b)(2)(i), effective April 26, 1976.

16. On March 16, 1976 the Department of Health, Education and Welfare promulgated to all state agencies administering the Medical Assistance Program an "Information Memorandum" with specific references to 45 C.F.R. 250.30 (b)(2). On page 7 of said "Pre-Publication Draft Guidelines On Payment For Drugs Under the Medicaid Program" attached to said "Information Memorandum" it is stated:

Dispensing Fee

The dispensing fee will still be established by each State. However, the new regulations mandate that "States shall"

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periodically conduct...surveys of pharmacy operational data including such components as overhead, professional services and profits." Fees established by the States do not have to exactly match results from the surveys. In order to achieve equitable reimbursements for pharmacists, as well as enlisting adequate participation in the Medicaid program, it is imperative that States assign sufficient weight to the survey results in establishing dispensing fees. States are urged to utilize survey results to develop equitable and reasonable fees.

17. The dispensing fee established by the State of New York, which plaintiffs believe is the amount of \$1.80 and which plaintiffs further believe has not been modified since 1968, is in violation of the aforementioned statutes and regulations of the United States because the defendants did not take into account the results of surveys of pharmacy operations costs, including overhead, professional services, and profits, as required by Title XIX of the Social Security Act, 42 U.S.C. Section 1396 et seq. and the regulations promulgated thereunder.

18. The continued administration of the New York State Medical Assistance Program by the defendants which incorporates the aforementioned unreasonable, unlawful and inequitable dispensing fee is presently interfering with the legal rights and privileges of the individual plaintiffs, and they are being irreparably harmed thereby due to the adverse economic impact of the defendants' failure to comply with the aforementioned statutes and regulations of the United States. Due to the large number of transactions involved, and the continuing nature of such transactions, the plaintiffs have no adequate remedy at law; and all plaintiffs pray for a declaratory judgment holding said regulation unconstitutional and void, and for a preliminary and permanent injunction against its continued enforcement and administration.

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SECOND COUNT

19. On or about ~~February~~ 15, 1976 the plaintiffs believe that the United States Department of Health, Education and Welfare promulgated the ~~first~~ Federal Price Guidelines (E.A.C. price list) which plaintiffs further believe, as applied to pharmaceutical providers in the State of New York, violates with the drug reimbursement provisions of the Medicaid and Medicare statutes, each of which require that drug reimbursement be based upon the "reasonable cost" of the drugs provided or that reimbursement be based upon "reasonable charges" for such drugs.

42 U.S.C. 1395 f.(b); 42 U.S.C. 1395 l (a)(1)(2); 42 U.S.C. 1395 (a)-(13) (D); 42 U.S.C. 1395 x (v)(1)(a); 42 U.S.C. 1396 a (a) (30); 42 U.S.C. 1395 u (2)(3); 42 U.S.C. 1396 b (1)(1).

20. The E.A.C. regulations and the February 15, 1976 Federal E.A.C. price list violates from such provisions as applied to the State of New York in that the prices listed therein are substantially below the reasonable cost of such drugs to plaintiffs in the State of New York.

21. On or about ~~August~~ 25, 1976 the New York State Department of Social Services adopted in toto the aforementioned Federal price guidelines (Department of Health Education and Welfare E.A.C. price list).

22. The promulgation and implementation of the federal price guidelines by the New York State Department of Social Services further violates the Medicaid and Medicare statutes in that such action will necessarily reduce the quality and availability of pharmaceutical services available to recipients under the said public welfare programs and will not be "in the best interests of the recipients" as required by such statute 42 U.S.C. 1396 (a)(19).

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23. The E.A.C. regulations and the implementation thereof by the defendants in the State of New York on or about August 26, 1976 violates the federal regulations recently promulgated and published at 45 C.F.R. 19.2 (f) and 19.3, effective on the same date, which require that reimbursement for drugs used in the aforesaid public welfare program shall be based upon "acquisition cost" defined as "the price generally and commonly paid by providers"; The E.A.C. and the Federal Price Guidelines as applied by the defendants in the State of New York do not reflect the prices generally currently paid by pharmaceutical providers in New York State; nor have the defendants provided for any regulatory scheme to permit said price guidelines to be maintained in current and accurate form.

24. Claiming to act pursuant to the requirements of 49 C.F.R. 250/30 (b)(2), the defendant CAREY and the defendant TOIA promulgated, on or about August 25, 1976 an administrative letter designated "Transmittal No. 76 AEX-85" which purported to promulgate regulations amending the State of New York's Medical Assistance Program by adopting M.A.C. and E.A.C. upper limits on payments to pharmaceutical providers, and by continuing the dispensing fee which was neither reviewed nor modified and which is at the same rate as it was in 1968, to wit, One dollar and 80/100 (\$1.80).

25. The E.A.C. regulations and price list promulgated by the New York State Department of Social Services are unlawful because they are arbitrary, unreasonable and not supported by substantial evidence that they are New York State's closest estimate of the prices generally and commonly paid by providers as required by Title XIX of the Social Security Act, 42 U.S.C. 1396 et seq., and the regulations promulgated thereunder; but

rather, plaintiffs believe they are based upon the aforementioned Federal Price Guidelines and other information made available by the Department of Health, Education and Welfare on acquisition costs incurred by wholesalers or retail pharmacists who are purchasing drugs from manufacturers, rather than upon acquisition costs incurred by retail pharmacists when purchasing drugs from wholesalers.

26. Since on or about August 26, 1976, the plaintiffs, STILL'S PHARMACY, INC., RIS-WALD PHARMACY, INC., and M.F.X. CO., INC. have each filed claims with their respective county or city departments of social services. Plaintiffs believe that each such county department of social services has been mandated to comply with the provisions of the aforementioned "Transmittal No. 76 ADM-88" promulgated by the defendants.

27. Prior to the issuance of said administrative transmittal letter, the defendants had reimbursed retail pharmacists participating in the Medicaid Program administered locally by the county and city social services departments for all drugs provided by them to recipients under the Medicaid Program by paying said retail pharmacists the average wholesale price of the drugs, plus a dispensing fee.

28. Effective on August 26, 1976, pursuant to the provisions of "Transmittal No. 76 ADM-88" the defendants decreased the level of reimbursement to participating providers by paying them the E.A.C. price for non-multi-source drugs in spite of the fact that said E.A.C. prices promulgated by the defendants are inaccurate and unreasonable.

29. Each of the foregoing individuals and all persons similarly situated have suffered and will continue to suffer substantial damages in excess of Ten thousand (\$10,000.00) Inclusive.

exclusive of interest and cost due to the continued enforcement by the defendants of said invalidly promulgated E.A.C. price list.

30. Unless the defendants are restrained and enjoined from implementing in the State of New York, the United States Department of Health, Education and Welfare's national price guidelines and other such lists, the plaintiffs and all other pharmacists similarly situated who continue to provide pharmaceutical services and supplies pursuant to the Medicaid and Medicare programs will suffer substantial and incalculable monetary losses and be subjected to unwarranted interference in the practice of their profession.

31. If the defendants are not so restrained or enjoined, numerous pharmacists may find it necessary to refuse to provide such medical assistance, not out of desire but because of sheer inability to participate in and support public welfare programs; and untold pharmacists and retail drug stores, as well as wholesalers, may be forced out of business entirely thereby reducing the quality and availability of pharmaceutical services to both the public and to medicaid program recipients and presenting additional administrative burdens and costs.

32. The plaintiffs have exhausted all available administrative remedies with respect to E.A.C. and have no prompt, adequate, and effective remedy at law.

THIRD COUNTER

33. The defendants' Transmittal No. 76 ABM-88 contained a directive or regulation of the New York Department of Social Services that the New York State E.A.C. price shall be the price of the drug as it appears in the State E.A.C. list or

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... the Red Book price (as defined by Transmittal No. 71 ARY-88) minus 2% plus a dispensing fee.

34. Said directive or regulation is arbitrary, unreasonable and unlawful and not supported by substantial evidence that it is an accurate and reasonable formula of New York State's closest estimate of the prices generally and commonly paid by providers as required by Title XIX of the Social Security Act, 42 U.S.C. 1396 et seq., and the regulations promulgated thereunder; but rather, plaintiffs believe that it is an arbitrary and inaccurate formula, calculated to merely promote administrative expediency rather than an accurate and substantial compliance with the aforementioned statute and the regulations promulgated thereunder.

35. Said regulation is, furthermore, an unconstitutional deprivation of plaintiffs' property without due process of law.

FOURTH COUNT

36. The administration of the E.A.C. regulations and the E.A.C. price list promulgated by the defendants in the State of New York are unconstitutional and void in that they arbitrarily establish, without providing prior notice or hearing or subsequent notification of, the amount which a participating provider may charge for his professional services and supplies thereby denying participating providers equal protection under the law and depriving them of their property without due process of law;

37. The E.A.C. price lists promulgated by the New York State Department of Social Services are unconstitutional and void because they are arbitrary, unreasonable and unsupported by substantial evidence establishing that they are

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New York State's closest estimate of the prices generally and currently paid by pharmaceutical providers as required by Title XIX of the Social Security Act, 42 U.S.C. 1396 et seq. and the regulations promulgated thereunder, but rather, plaintiffs believe, they are based upon the Federal price guideline information made available by the Department of Health, Education and Welfare on acquisition costs throughout the United States rather than upon acquisition costs actually incurred by retail pharmacists when purchasing drugs from wholesalers in the State of New York.

38. Plaintiffs further allege that the defendants have acted in violation of their rights and privileges under the Fifth and Fourteenth Amendments to the United States Constitution in that the defendants have failed to permit and have directed the various social service districts (various counties and cities of the State of New York) not to permit the plaintiffs and all other pharmaceutical providers similarly situated, to inspect, obtain or review the very New York State E.A.C. price lists under which the plaintiffs are now required to provide pharmaceuticals under the Medicaid program in the State of New York.

FIFTH COUNT

39. The continued enforcement of the present dispensing fee in the State of New York by the defendants is confiscatory; is presently interfering with and jeopardizing the legal rights and privileges of the plaintiffs; and is a deprivation of their property without due process of law.

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SIXTH COUNT

40. Since on or about September 1, 1976 and continuing thereafter, the plaintiffs have implemented and promulgated, and continue to implement and promulgate, the New York State Department of Social Services' E.A.C. rules and price lists in violation of the New York State Administrative Procedure Act, Sections 201 and 202 (2), in that the Department of Social Services, an agency as defined by said Act, failed prior to the "adoption or amendments" of a rule of general applicability, to "give or cause to be given, notice and offer any person or other agency an opportunity to present data, views or arguments"

41. In so failing to comply with the provisions of said act defendants did substantially injure the plaintiffs herein, who have no prompt, adequate, and effective remedy at law.

SEVENTH COUNT

42. The defendants have also blatantly violated the provisions of the New York State Administrative Procedure Act, Section 511 (1), as well as the Fifth and Fourteenth Amendments of the Constitution of the United States as hereinabove set forth in the THIRD COUNT, since on or about September 1, 1976, by specifically and unlawfully directing that:

Districts (individual N.Y.S. county or city social services departments) should not forward a copy of the State E.A.C. list to pharmacists.

WHEREFORE, plaintiffs demand:

1. A declaratory judgment:

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(a) holding ~~the~~ provisions of Transmittal No. 76 ABM-88, and any and all ~~subsequent~~ New York State E.A.C. regulations and price lists ~~presented~~ or based upon said document, unconstitutional, unlawful, ~~null~~ and void.

(b) specifically holding the rule or regulation of the New York State Department of Social Services, fully set forth and defined hereinabove in the THIRD COUNT, unconstitutional, unlawful, null and void.

(c) holding ~~the~~ current pharmaceutical provider dispensing fee in the State of New York unconstitutional, unlawful, null and void.

(d) holding ~~the~~ directive of the defendants, or their agents, to the local ~~districts~~ participating in the New York State Medical Assistance Program that the pharmaceutical providers are not to be provided a copy of the State E.A.C. list, unconstitutional, unlawful, ~~null~~ and void.

2. That the ~~defendants~~, their respective agents and employees, and all other persons subject to their control be enjoined and restrained ~~during~~ the pendency of this action, and perpetually thereafter, ~~from~~:

(a) implementing, enforcing, or acting in reliance upon the current E.A.C. price list of the New York Department of Social Services, and other E.A.C. price lists promulgated by the New York State Department of Social Services, specifically including each and every part of Transmittal No. 76 ABM-88, until such time as defendants fully comply with the provisions of 42 U.S.C. 1396 et seq.; 45 C.F.R. 250.30 (b)(2); 45 C.F.R. 19.2 (f) and 19.3.

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(b) implementing, enforcing, or acting in reliance upon the specific New York State E.A.C. regulation that the E.A.C. price shall be the price of the drug as it appears in the State E.A.C. list plus a dispensing fee or when no price is shown on the State E.A.C. list the Red Book price (as defined by Transmittal No. 76 ABM-88) minus 27 plus a dispensing fee.

(c) continuing enforcing, performing, and acting in reliance upon the current pharmaceutical provider dispensing fee of One and 80/100 (\$1.80) Dollar.

3. That defendants be ordered to:

(a) revise, correct and modify the New York State E.A.C. price list to comply with the mandate of 42 U.S.C. 1396 et seq.; and the aforementioned regulations promulgated thereunder.

(b) revise, correct and modify in an expedited manner, taking into account the results of surveys of costs of pharmacy operations within the State of New York, the current pharmaceutical provider "dispensing fee" in compliance with 42 U.S.C. 1396 et seq.; 35 C.F.R. 250.30 (b)(2), 45 C.F.R. 19.3 and the Department of Health, Education and Welfare's "Guidelines on Payments for Drugs Under the Medicaid Program" (Medical Assistance Manual) promulgated pursuant to 45 C.F.R. 250.30 (b)(2).

(c) periodically conduct surveys of the costs of pharmacy operational data pursuant to 45 C.F.R. 250.30 (b)(2)(1) to assure continued compliance with the aforementioned regulation.

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(d) give ~~any~~ cause to be given, notice and offer the plaintiffs and ~~any~~ person or other agency an opportunity to present data, views and arguments prior to the adoption, amendment, suspension or repeal of any rule or regulation of general applicability regarding the Medicaid Medical Assistance Program as defined in 42 U.S.C. 1396 et seq., in the State of New York.

(e) provide, distribute and circulate all regulations and price lists promulgated in the State of New York by defendants pursuant to 42 U.S.C. 1396 et seq. to all pharmaceutical providers, as defined in 45 C.F.R. 19.2.

4. That defendants pay to plaintiffs the costs and disbursements of this action, including an allowance for attorneys's fees.

5. That plaintiffs have such other, further, and different relief as the Court may deem just and proper.

GOLDBERG & GOLDBERG
Attorneys for Plaintiffs

By Lloyd Sneedberg
A Member of the Firm

999 Central Avenue
Woodmere, New York 11598
Tel: 516-374 4694